REMARKS

Claims 1-15 were originally presented. New claims 16-19 were presented in the response filed December 17, 2007. Claims 1-8, and 18 were revised and new claims 20-21 were submitted in the response filed August 15, 2008. Claims 6, 8, 16, 18 and 19 were amended in the supplemental amendment to Request for Continued Exam, filed on November 5, 2008. Claims 1 and 2 were amended in the response filed February 25, 2010 to better define the invention. The claims presently under consideration are thus claims 1-21, as set forth herein. These claims are supported by the specification as filed, and Applicant believes that no new matter has been added. Applicant respectfully requests that the Examiner reconsider and withdraw the various grounds of rejection of the claims.

I. Priority

On page two of the Office Action, the Examiner states that Claim 16 is determined to have a priority date of June 5th 2003. The Examiner states: "Claim 16 does not find support in the provisional application 60/385,571 [...]" Applicant requests clarification. Specifically, for what element of Claim 16 is the Examiner alleging this lack of support? Also, does this mean that claims 1-15 and 17-21 are understood to have a priority date of June 5th, 2002? If so, does this also mean that with cancellation of claim 16 the Examiner agrees that the Raut reference is not applicable?

II. Withdrawn Rejections

35 USC 103(a)

The Examiner has withdrawn the rejection of Claims 2-3 and 21 under 35 USC 103 as being unpatentable over Resnick. (US 2002/0141760) (hereinafter "Resnick"); Ding (PSTT, Vol. 1, No. 8, Nov 1998) (hereinafter "Ding"); Vandamme (Progress in Retinal and Eye Research 21 (2002) 15-34) (hereinafter "Vandamme"); Nagarsenker et al (Int. Journal of Pharmaceutics 190 (1999) 63-71) (hereinafter "Nagarsenker"); and Paul et al (Current Science, Vol. 80, No8, 25 April 2001) (hereinafter "Paul"). Applicant acknowledges this withdrawn rejection.

35 USC 112, second paragraph

The Examiner has withdrawn the rejection of claims 1-21 under 35 USC 112, second paragraph. Applicant acknowledges this withdrawn rejection.

III Maintained Rejections

103(a)

Claims 1, 4-5, 7-15 and 20 remain rejected under 35 USC 103 as being unpatentable over Resnick; Ding; Vandamme; Nagarsenker; and Paul. The Examiner states that as to claims 1, 4, 9 and 12: "Resnick teaches a contact lens containing nanospheres that are incorporated directly therein [...] Resnick further teaches methods of incorporating drugs and therapeutic agents into the contact lens for the purpose of drug delivery to the eye [...] as well as a kit [...]". The Examiner cites Ding for the proposition that it was known in the art that nanoparticles could be utilized to provide sustain drug release and prolonged therapeutic activity for delivery of either hydrophobic or hydrophilic ophthalmic drugs. The Examiner refers to Vandame for the teaching of micro emulsions as ocular drug delivery systems. The Examiner further refers to Paul for the teaching that micro-emulsions allow sustained release of controlled drug release for ocular administration. The Examiner refers to Nagarsenker for the teaching of preparation and evaluation of liposomal formulations for ocular delivery. The Examiner states that both Vandamme and Nagarensker teach encapsulation materials, liposomes and micro emulsions that can be used with hydrophobic or lipophilic.

Claims 6 and 17-19 remain rejected under 35 USC 103 as being unpatentable over Resnick; Ding; Vandamme; Nagarsenker; and Paul and further in view of Darouger et al (US 6,264,971) (hereinafter "Darouger "). The Examiner states that Darougar teaches an ocular insert that releases an ophthalmic drug in a controlled, sustained fashion.

Claims 6 and 16 remain rejected under 25 USC 103 as being unpatentable over Resnick; Ding; Vandamme; Nagarsenker; and Paul and further in view of Raut (US 2003/0216431, filed 8/1/2002). The Examiner states that Raut teaches ophthalmic pharmaceutical compositions for topical administration to the eye.

IV New Rejections

103(a)

The Examiner newly rejects claims 2-3 and 21 under 35 USC 103(a) as being unpatentable over Resnick Ding; Vandamme; Nagarsenker; and Paul and further in view of Ghosh, Indian Journal of Biochemistry and Biophysics, Vol 37, October 2000, Pg 273-282) The Examiner states that Ghosh teaches the use of polymeric nanoparticles as drug particles.

V Analysis

In order to anticipate a claimed invention, a prior art reference must enable one of ordinary skill in the art to make the invention without undue experimentation. Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323, 1336 (Fed. Cir. 2008) (citing In re Omeprazole Patent Litig., 483 F.3d 1364, 1379 (Fed. Cir. 2007)). In other words, the prior art must enable the claimed invention. Minn. Mining & Mfg. Co. v. Chemque, Inc. (3M), 303 F.3d 1294, 1301 (Fed. Cir. 2002). Factors to consider in determining undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed.Cir. 1991) (discussing application of the Wands factors).

The 2010 KSR Guidelines Update as published by the Office of Patent Legal Administration includes the teaching, suggestion, and motivation test as a rationale "to support an obviousness determination". Other rationales are also proposed including: (1) combining prior art elements according to known methods to yield predictable results; (2) simple substitution of one known element for another to obtain predictable results; (3) use of a known technique to improve similar devices, methods, or products in the same way; (4) applying a known technique to a known device, method or product ready for improvement to yield predictable results; (5) "obvious to try"; and (6) known work in one field of endeavor may prompt variation of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to a person of ordinary skill in the art. A constant through these tests is the term "known"; for example, "known method", "known technique", and "known element".

Similarly, the Federal Circuit has cautioned that an obviousness inquiry based on an obvious to try rationale must always be undertaken in the context of the subject matter in question, "including the characteristics of the science or technology, its state of advance, the nature of the known choices, the specificity or generality of the prior art, and the predictability of results in the area of interest." Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1352 (Fed. Cir. 2008).

As Applicant has previously stated, ALL the cited references (except Resnick) focus on ophthalmic drug delivery through ocular formulations that contain nanoparticles

such as microemulsions or liposomes dispersed in aqueous solutions. These systems are fundamentally different from dispersions of the nanoparticles in the contact lenses. The sole reference allegedly providing disclosure for a drug delivery system encompassing a contact lens have dispersed therein as nanoparticles, an ophthalmic drug encapsulated in a material from which the ophthalmic drug is capable of diffusion into and migration through the contact lens and into the post-lens tea film when the contact lens is place on the eye is Resnick. However, the focus and intent of Resnick's invention is very different from that of the current invention. Resnick does not enable a person of ordinary skill to load nano/microspheres into contact lenses for the purpose of extended drug delivery.

The Examiner states that paragraphs 0003 and 0006 of Resnick "teach" a contact lens containing nanospheres that are incorporated directly therein. Applicant provides these paragraphs below in their respective entireties:

> [0003] The instant application and invention relates to a means, method and manufacture of a contact lenses designed to be worn on the user's eye for the purpose of providing protection from the effects of repeated exposure to optical stimulation of the optic nerves and central nervous system, or brain, as a result of repeated exposure to flashes of radiant light commonly associated with the strobe flashes produced by cameras, or by exposure to radiation from other sources, such as the Sun, or from next-generation LASER or spectral energy weapons, or any type of electromotive force weaponry, by providing and incorporating, singularly or in combination, both methods of reflective means and/or adsorptive means utilizing Radar-Attenuating Materials ("RAM), such as Molybdenum Disulfide ("MOS2"), or other discrete microelectronic devices, such as electromotive force ("EMF") counter counter-measure devices, in order to protect the wearer from suffering injuries or harm as a result of exposure to such occurrences. In a less severe example, celebrities and movie stars are exposed to hundreds of flashes during special events such as the Screen Actor's Guild Award ceremonies, Oscar presentations and awards, etc. During such events and as a result of repeated exposure to the flashes generated by cameras used by members of the media and the Paparazzi, some celebrities experience physical side effects as a result of over stimulation to the optic nerves and central nervous system (brain), such as disorientation, temporary blindness, vertigo, nausea/vomiting, etc. One of the objects of the instant invention is to prevent such physical onsets of discomfort, symptoms and possible side effects, such as development of

brain tumors, as a result of such exposure to unnatural light sources. The instant invention is enabled through alteration and improvement of conventional contact lenses by incorporation of the microspheres or nanospheres into the actual lens during manufacture through fabrication of a new shaped matrix incorporating microspheres (including nanospheres) containing reflective or adsorptive substances, or by the application of a coating comprising substrate, carrier microspheres, binder and chemicals, in a matrix or comprising layers of coating comprising a matrix, or comprising a series of matrixes, to be applied as a coating to existing lenses or new manufactures, or alternately to both.

[0006] The instant invention comprises a typical permeable, or semi-permeable, or gas permeable (breathable), or conventional glass, or hard contact eye lenses as taught in U.S. Pat. Nos. 5,891,932 or 4,865,439, for example. These types of contact eye lenses have been the subject of much study and research and their value to users has been well established by the medical, scientific and academic communities. The novel contact eye lens proposed by the Instant Invention differs from conventional contact eye lenses in that the instant invention now provides a means and method of placing both reflective coatings on the transverse or inner surface of the contact eye lenses, in one embodiment, for example, or by incorporating an energy-absorbent substance directly into the lens (via microspheres or nanospheres) during the manufacture process, or through creation of a matrix or matrixes containing energy-absorptive substances or energy reflective substances, or combination thereof, which enables the wearer to protect against potentially harmful radiant energies, whether naturally produced from the Sun, for example, or from directed energy sources such as LASER weapons, or other such EMF or spectra-specific Less-Than-Lethal ("LTL's) weapons, such as sound or light guns in present use and experimentation by the U.S. Marine's Light Urban Assault Task Forces, Quantico, Va., USA. Reference is now made to U.S. patent application Ser. No. 09/312,535 Filed on May 24, 1999 Entitled, Close-Contact Counter-Measure Garment, being examined in Art Unit 3644 by Examiner J. Eldred, and incorporated herein by reference as if by its entirety.

As shown, paragraph [0003] relates to a means of blocking light transmission, effectively relating to a contact lens that can be used instead of sunglasses. Paragraph [0003] does not provide any disclosure related to drug delivery. Similarly, paragraph

[0006] provides absolutely NO mention of a new means for providing extended or time-release delivery of an ophthalmic drug.

The Examiner further cites to paragraph 0019 and claim 2 as teaching a method of incorporating drugs and therapeutic agents into a contact lens for the purpose of drug delivery. Paragraph [0019] reads as below:

> [0019] A further aspect of the invention is a novel chemical or gas delivery system which may be used in combination with the instant system to accomplish levage of the organ (eye) or to treat injuries by application of time-released substances directly onto the surface of the cornea or to the overall surface of the organ (eye), after or prior to injury, or during incidences of battle, for example, or while recovering from eye or facial surgery or injuries. I shall cause the filing of a separate patent application, without traverse, concerning this aspect of the invention, but mention it here, only to document discovery and concept dates as a matter of record.
>
> Claim 2 The device of claim 1, comprising a method of presenting microspheres containing adsorptive or reflective, or heating and cooling properties, entropic or enthalpic, or drug delivery properties to a part or parts of the human body, to the eye.

The above cannot possibly be seen as an enabling disclosure. Stating a proposition and teaching are two separate things. Applicant could easily state a proposition for a perpetual motion machine. Teaching such a machine would be a different matter. One of ordinary skill in the art, attempting to practice the present invention based upon the disclosure of Resnick would not have had a reasonable expectation of success. In addition, the Resnick disclosure is so limited that there is no mention of: methods/means of encapsulation, synthesis procedures for microemulsions, synthesis procedures for liposomes, drug release studies, transparency studies, structure studies, drug diffusion studies, loading studies, drug release studies, development of time scale equations, or hydrogel studies. These and more were performed by Applicant through the inventive process and were included in Applicant's enabling disclosure.

In the alternative, Applicant further notes evidence of conception plus reasonable diligence to reduction to practice. Applicant directs the Examiner to the enclosed Declaration with Attachments A, B, and C.

Attachment A provides a document originally provided to University of Florida as part of the application process for a position as an Associate Professor in the department of chemical engineering. Based upon the inventor's computer records this document was last modified on February 3, 2000 and was submitted to University of Florida approximately mid-February, 2000. Thus, this document pre-dates the March 29, 2001 filing date of Resnick.

Applicant was hired by the University of Florida and initiated his tenure as an Associate Professor the Fall term of 2000. Attachment B provides a copy of a document distributed to graduate students at the University of Florida. The document was used in selecting the students that assisted with the research. Based upon the inventor's computer records this document was last modified on October 20, 2000. Thus, this document also pre-dates the March 29, 2001 filing date of Resnick.

Attachment C is the invention disclosure that was submitted to the University of Florida Office of Technology Licensing. The document was submitted on October 23, 2001 and received October 29, 2001. This document provides further evidence of continued diligence related to this invention.

Applicant has earnestly endeavored to place the application in condition for allowance and favorable action toward that end is respectfully requested. The Commissioner is hereby authorized to charge to Deposit Account No. 50-1165 (T2315-908542US02) any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper and to credit any overpayment to that Account. If any extension of time is required in connection with the filing of this paper and has not been separately requested, such extension is hereby requested.

Respectfully submitted,

Date: December 20, 2010

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